

## **Amendments to the Claims**

Please amend the identified patent application by deleting the claims filed with the application and entering the following claims for examination. Please note the remarks below. Please also accept the enclosed Terminal Disclaimer to obviate any possible obviousness-type double patenting issue relative to U.S. Patent No. 6,669,663.

This listing of claims will replace all prior versions, and listings, of claims in the application:

### **Listing of Claims:**

Claims 1-13: (**Cancelled**)

Claim 14. (New) A closed loop medicament pump system for a patient for sampling and determining the concentration of a substance of interest through the patient's skin and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

an iontopheretic sensor module for sampling and detecting a concentration of a substance of interest through skin, wherein the sensor module comprises a sampling system and a concentration determining system;

a control system, responsive to the iontopheretic sensor module, for determining a response to the sampled and determined concentration of a substance of interest;

a sensor telemetry system for transmitting information regarding the response determined by the control system through the patient's body;

a pump telemetry system for receiving information regarding the response determined by the control system through the patient's body and for communicating the information to an implantable drug pump; and

an implantable drug pump, acting in response to the information communicated to the implantable drug pump from the pump telemetry system, to deliver a responsive dose of an appropriate medicament to the patient.

Claim 15. (New) A closed loop medicament pump system according to claim 14 wherein the sensor module is an external sensor.

Claim 16. (New) A closed loop medicament pump system according to claim 14 wherein the sensor module is disposable.

Claim 17. (New) A closed loop medicament pump system according to claim 14 wherein the sensor module is reusable.

Claim 18. (New) A closed loop medicament pump system according to claim 14 wherein the sensor module is attached to a flexible substrate.

Claim 19. (New) A closed loop medicament pump system according to claim 18 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 20. (New) A closed loop medicament pump system according to claim 14 wherein the control system is a microprocessor.

Claim 21. (New) A closed loop medicament pump system as in claim 20, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 22. (New) A closed loop medicament pump system as in claim 21, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 23. (New) A closed loop medicament pump system as in claim 21, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of

the substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 24. (New) A closed loop medicament pump system as in claim 23, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 25. (New) A closed loop medicament pump system as in claim 23, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 26. (New) A closed loop medicament pump system as in claim 21, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 27. (New) A closed loop medicament pump system as in claim 21, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 28. (New) A closed loop medicament pump system as in claim 20, in which the microprocessor further includes a memory with a look-up table for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 29. (New) A closed loop medicament pump system as in claim 20, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 30. (New) A closed loop medicament pump system as in claim 29, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 31. (New) A closed loop medicament pump system as in claim 20, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 32. (New) A closed loop medicament pump system as in claim 31, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 33. (New) A closed loop medicament pump system as in claim 31, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 34. (New) A closed loop medicament pump system as in claim 33, further comprising uplink telemetry equipment.

Claim 35. (New) A closed loop medicament pump system as in claim 14, the drug pump acting in response to communication to the drug pump by body bus.

Claim 36. (New) A closed loop medicament pump system as in claim 14, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 37. (New) A closed loop medicament pump system as in claim 14, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 38. (New) A closed loop medicament pump system as in claim 14, further comprising an operatively connected battery.

Claim 39. (New) A closed loop medicament pump system, pump or medical device as in claim 38 wherein the battery is a flexible battery.

Claim 40. (New) A closed loop medicament pump system as in claim 14, in which the control system is located with the drug pump.

Claim 41. (New) A closed loop medicament pump system as in claim 14, in which the control system is located with the sensor module.

Claim 42. (New) A closed loop medicament pump system according to claim 14 wherein the substance of interest includes glucose and the sensor module samples and detects a concentration of the substance of interest including glucose.

Claim 43. (New) A closed loop medicament pump system according to claim 14 wherein the appropriate medicament is insulin, and the drug pump delivers insulin.

Claim 44. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest through the patient's skin and for determining and delivering a responsive dose of an appropriate medicament to the patient, wherein the substance of interest includes glucose and the medicament includes insulin, comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the implantable drug pump.

Claim 45. (New) A closed loop medicament pump according to claim 44 wherein the sensor module is an external sensor.

Claim 46. (New) A closed loop medicament pump according to claim 44 wherein the sensor module is disposable.

Claim 47. (New) A closed loop medicament pump according to claim 44 wherein the sensor module is reusable.

Claim 48. (New) A closed loop medicament pump according to claim 44 wherein the sensor module is attached to a flexible substrate.



Claim 49. (New) A closed loop medicament pump according to claim 48 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 50. (New) A closed loop medicament pump according to claim 44 wherein the control system is a microprocessor.

Claim 51. (New) A closed loop medicament pump as in claim 50, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 52. (New) A closed loop medicament pump as in claim 51, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 53. (New) A closed loop medicament pump as in claim 51, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the

substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 54. (New) A closed loop medicament pump as in claim 53, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 55. (New) A closed loop medicament pump as in claim 53, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 56. (New) A closed loop medicament pump as in claim 51, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 57. (New) A closed loop medicament pump as in claim 51, in which the pump includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 58. (New) A closed loop medicament pump as in claim 50, in which the microprocessor further includes a memory with a look-up table for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 59. (New) A closed loop medicament pump as in claim 50, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 60. (New) A closed loop medicament pump as in claim 59, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 61. (New) A closed loop medicament pump as in claim 50, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 62. (New) A closed loop medicament pump as in claim 61, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 63. (New) A closed loop medicament pump as in claim 61, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 64. (New) A closed loop medicament pump as in claim 63, further comprising uplink telemetry equipment.

Claim 65. (New) A closed loop medicament pump as in claim 44, the drug pump acting in response to communication to the drug pump by body bus.

Claim 66. (New) A closed loop medicament pump as in claim 44, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 67. (New) A closed loop medicament pump as in claim 44, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 68. (New) A closed loop medicament pump as in claim 44, further comprising an operatively connected battery.

Claim 69. (New) A closed loop medicament pump as in claim 68 wherein the battery is a flexible battery.

Claim 70. (New) A closed loop medicament pump as in claim 44, in which the control system is located with the drug pump.

Claim 71. (New) A closed loop medicament pump as in claim 44, in which the control system is located with the sensor module.

Claim 72. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest and for determining and delivering a responsive dose of an appropriate medicament to the patient, wherein the substance of interest includes glucose and the medicament includes insulin, comprising:

a sensor for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient;

a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and,

a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump.

Claim 73. (New) A closed loop medicament pump system according to claim 72 wherein the sensor module is an external sensor.

Claim 74. (New) A closed loop medicament pump according to claim 72 wherein the sensor module is disposable.

Claim 75. (New) A closed loop medicament pump according to claim 72 wherein the sensor module is reusable.

Claim 76. (New) A closed loop medicament pump according to claim 72 wherein the sensor module is attached to a flexible substrate.

Claim 77. (New) A closed loop medicament pump according to claim 76 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 78. (New) A closed loop medicament pump according to claim 72 wherein the control system is a microprocessor.

Claim 79. (New) A closed loop medicament pump as in claim 78, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 80. (New) A closed loop medicament pump as in claim 79, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 81. (New) A closed loop medicament pump as in claim 79, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 82. (New) A closed loop medicament pump as in claim 81, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 83. (New) A closed loop medicament pump as in claim 81, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 84. (New) A closed loop medicament pump as in claim 79, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 85. (New) A closed loop medicament pump as in claim 79, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 86. (New) A closed loop medicament pump as in claim 78, in which the microprocessor further includes a memory with a look-up table for the responsive dose of



the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 87. (New) A closed loop medicament pump as in claim 78, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 88. (New) A closed loop medicament pump as in claim 87, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 89. (New) A closed loop medicament pump as in claim 78, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 90. (New) A closed loop medicament pump as in claim 89, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 91. (New) A closed loop medicament pump as in claim 89, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 92. (New) A closed loop medicament pump as in claim 91, further comprising uplink telemetry equipment.

Claim 93. (New) A closed loop medicament pump as in claim 72, the drug pump acting in response to communication to the drug pump by body bus.

Claim 94. (New) A closed loop medicament pump as in claim 72, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 95. (New) A closed loop medicament pump as in claim 72, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 96. (New) A closed loop medicament pump as in claim 72, further comprising an operatively connected battery.

Claim 97. (New) A closed loop medicament pump as in claim 96 wherein the battery is a flexible battery.

Claim 98. (New) A closed loop medicament pump as in claim 72, in which the control system is located with the drug pump.

Claim 99. (New) A closed loop medicament pump as in claim 72, in which the control system is located with the sensor module.

Claim 100. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest and for determining and delivering a responsive dose of an appropriate medicament to the patient, wherein the substance of interest includes glucose and the medicament includes insulin, comprising:

an external, disposable, reusable sensor for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system including a microprocessor for determining an appropriate response to the determined concentration of the substance of interest, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration, and generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament, and if the comparing step indicates the concentration does not exceed the predetermined limit,

waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program or programmed, and in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command, in which the microprocessor further includes one of either a memory with a look-up table or a formula for the responsive dose of the appropriate medicament or a memory , and the step of determining the responsive dose includes one of retrieving a value from the look-up table or determining the dose according to the formula;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory with related time of the delivery of the responsive dose, and the memory keeps the information and time available for later uplink telemetry;

uplink telemetry equipment including an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer;

a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and,

a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump;

and an operatively connected battery.

Claim 101. (New) A closed loop medicament pump system as in claim 100, in which the control system is located with the drug pump.

Claim 102. (New) A closed loop medicament pump system as in claim 100, in which the control system is located with the sensor module.

Claim 103. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest and for determining and delivering a responsive dose of an appropriate medicament, wherein the substance of interest includes glucose and the medicament includes insulin, to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient; and

a telemetry system for communicating information from the control system to the implantable drug pump.

Claim 104. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest and for determining and delivering a responsive dose of an appropriate medicament, wherein the substance of interest includes glucose and the medicament includes insulin, to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being connected to the sensor module by a wire;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient; and

a telemetry system for communicating information from the control system to the implantable drug pump.

Claim 105. (New) A closed loop medical device for a patient for sampling and determining the concentration of a substance of interest including glucose in the patient and for taking an appropriate action in response thereto comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module;

a medical device for taking an action appropriate to a concentration of interest in a patient; and

a telemetry system for communicating information from the control system to the medical device.

Claim 106. (New) A closed loop medical device for a patient for sampling and determining the concentration of a substance of interest including glucose in the patient and for taking an appropriate action in response thereto comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being connected to the sensor module by a wire;

a medical device for taking an action appropriate to a concentration of interest in a patient; and

a telemetry system for communicating information from the control system to the medical device.

Claim 107. (New) A closed loop medical device for a patient for determining the concentration of a substance of interest including glucose in the patient and for taking an appropriate action in response thereto comprising:

means for determining the concentration of a substance of interest including glucose in the patient;



means for determining an appropriate response to the determined concentration of the substance of interest;

a medical device for taking an action appropriate to a concentration of interest in a patient;

means for communicating information from the means for determining the concentration to the means for determining an appropriate response; and,

means for communicating information from the means for determining an appropriate response to the medical device.

Claim 108. (New) A closed loop medicament pump system for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, through the patient's skin and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

an iontopheretic sensor module for sampling and detecting a concentration of a substance of interest through skin;

a control system, responsive to the iontopheretic sensor module, for determining a response to the sampled and determined concentration of a substance of interest;

a sensor telemetry system for transmitting information regarding the response determined by the control system through the patient's body;

a pump telemetry system for receiving information regarding the response determined by the control system through the patient's body and for communicating the information to an implantable drug pump; and

an implantable drug pump, acting in response to the information communicated to the implantable drug pump from the pump telemetry system, to deliver a responsive dose of an appropriate medicament to the patient.

Claim 109. (New) A closed loop medicament pump system according to claim 108 wherein the sensor module is an external sensor.

Claim 110. (New) A closed loop medicament pump system according to claim 108 wherein the sensor module is disposable.

Claim 111. (New) A closed loop medicament pump system according to claim 108 wherein the sensor module is reusable.

Claim 112. (New) A closed loop medicament pump system according to claim 108 wherein the sensor module is attached to a flexible substrate.

Claim 113. (New) A closed loop medicament pump system according to claim 112 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 114. (New) A closed loop medicament pump system according to claim 108 wherein the control system is a microprocessor.

Claim 115. (New) A closed loop medicament pump system as in claim 114, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 116. (New) A closed loop medicament pump system as in claim 115, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 117. (New) A closed loop medicament pump system as in claim 115, wherein the program further includes the step, if the comparing step indicates the concentration

does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 118. (New) A closed loop medicament pump system as in claim 117, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 119. (New) A closed loop medicament pump system as in claim 117, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 120. (New) A closed loop medicament pump system, pump or medical device as in claim 115, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 121. (New) A closed loop medicament pump system as in claim 115, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to

information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 122. (New) A closed loop medicament pump system as in claim 114, in which the microprocessor further includes a memory with a look-up table for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 123. (New) A closed loop medicament pump system as in claim 114, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 124. (New) A closed loop medicament pump system as in claim 123, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 125. (New) A closed loop medicament pump system as in claim 114, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 126. (New) A closed loop medicament pump system as in claim 125, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 127. (New) A closed loop medicament pump system as in claim 125, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 128. (New) A closed loop medicament pump system as in claim 127, further comprising uplink telemetry equipment.

Claim 129. (New) A closed loop medicament pump system as in claim 108, the drug pump acting in response to communication to the drug pump by body bus.

Claim 130. (New) A closed loop medicament pump system as in claim 108, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 131. (New) A closed loop medicament pump system as in claim 108, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 132. (New) A closed loop medicament pump system as in claim 108, further comprising an operatively connected battery.

Claim 133. (New) A closed loop medicament pump system as in claim 132 wherein the battery is a flexible battery.

Claim 134. (New) A closed loop medicament pump system as in claim 108, in which the control system is located with the drug pump.

Claim 135. (New) A closed loop medicament pump system as in claim 108, in which the control system is located with the sensor module.

Claim 136. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, through the patient's skin and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the implantable drug pump.

Claim 137. (New) A closed loop medicament pump according to claim 136 wherein the sensor module is an external sensor.

Claim 138. (New) A closed loop medicament pump according to claim 136 wherein the sensor module is disposable.

Claim 139. (New) A closed loop medicament pump according to claim 136 wherein the sensor module is reusable.

Claim 140. (New) A closed loop medicament pump according to claim 136 wherein the sensor module is attached to a flexible substrate.



Claim 141. (New) A closed loop medicament pump according to claim 140 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 142. (New) A closed loop medicament pump according to claim 136 wherein the control system is a microprocessor.

Claim 143. (New) A closed loop medicament pump as in claim 142, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 144. (New) A closed loop medicament pump as in claim 143, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 145. (New) A closed loop medicament pump as in claim 143, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the

substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 146. (New) A closed loop medicament pump as in claim 145, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 147. (New) A closed loop medicament pump as in claim 145, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 148. (New) A closed loop medicament pump as in claim 143, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 149. (New) A closed loop medicament pump as in claim 143, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 150. (New) A closed loop medicament pump as in claim 142, in which the microprocessor further includes a memory with a look-up table for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 151. (New) A closed loop medicament pump as in claim 142, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 152. (New) A closed loop medicament pump as in claim 151, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 153. (New) A closed loop medicament pump as in claim 142, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 154. (New) A closed loop medicament pump as in claim 153, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 155. (New) A closed loop medicament pump as in claim 153, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 156. (New) A closed loop medicament pump as in claim 155, further comprising uplink telemetry equipment.

Claim 157. (New) A closed loop medicament pump as in claim 136, the drug pump acting in response to communication to the drug pump by body bus.

Claim 158. (New) A closed loop medicament pump as in claim 136, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 159. (New) A closed loop medicament pump as in claim 136, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 160. (New) A closed loop medicament pump as in claim 136, further comprising an operatively connected battery.

Claim 161. (New) A closed loop medicament pump as in claim 160 wherein the battery is a flexible battery.

Claim 162. (New) A closed loop medicament pump as in claim 136, in which the control system is located with the drug pump.

Claim 163. (New) A closed loop medicament pump as in claim 136, in which the control system is located with the sensor module.

Claim 164. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

a sensor for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient;

a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and,

a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump.

Claim 165. (New) A closed loop medicament pump according to claim 164 wherein the sensor module is an external sensor.

Claim 166. (New) A closed loop medicament pump according to claim 164 wherein the sensor module is disposable.

Claim 167. (New) A closed loop medicament pump according to claim 164 wherein the sensor module is reusable.

Claim 168. (New) A closed loop medicament pump according to claim 164 wherein the sensor module is attached to a flexible substrate.

Claim 169. (New) A closed loop medicament pump according to claim 168 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 170. (New) A closed loop medicament pump according to claim 164 wherein the control system is a microprocessor.

Claim 171. (New) A closed loop medicament pump as in claim 170, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 172. (New) A closed loop medicament pump as in claim 171, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 173. (New) A closed loop medicament pump as in claim 171, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 174. (New) A closed loop medicament pump as in claim 173, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 175. (New) A closed loop medicament pump as in claim 173, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 176. (New) A closed loop medicament pump as in claim 171, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 177. (New) A closed loop medicament pump as in claim 171, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 178. (New) A closed loop medicament pump as in claim 170, in which the microprocessor further includes a memory with a look-up table for the responsive dose of



the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 179. (New) A closed loop medicament pump as in claim 170, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 180. (New) A closed loop medicament pump as in claim 179, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 181. (New) A closed loop medicament pump as in claim 170, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 182. (New) A closed loop medicament pump as in claim 181, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 183. (New) A closed loop medicament pump as in claim 181, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 184. (New) A closed loop medicament pump as in claim 183, further comprising uplink telemetry equipment.

Claim 185. (New) A closed loop medicament pump as in claim 164, the drug pump acting in response to communication to the drug pump by body bus.

Claim 186. (New) A closed loop medicament pump as in claim 164, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 187. (New) A closed loop medicament pump as in claim 164, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 188. (New) A closed loop medicament pump as in claim 164, further comprising an operatively connected battery.

Claim 189. (New) A closed loop medicament pump as in claim 188 wherein the battery is a flexible battery.

Claim 190. (New) A closed loop medicament pump as in claim 164, in which the control system is located with the drug pump.

Claim 191. (New) A closed loop medicament pump as in claim 164, in which the control system is located with the sensor module.

Claim 192. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient; and

a telemetry system for communicating information from the control system to the implantable drug pump.

Claim 193. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being connected to the sensor module by a wire;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient; and

a telemetry system for communicating information from the control system to the implantable drug pump.

Claim 194. (New) A closed loop medical device for a patient for sampling and determining the concentration of a substance of interest in the patient from among the group of biological chemicals, enzymes, and hormones, and for taking an appropriate action in response thereto comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module;

a medical device for taking an action appropriate to a concentration of interest in a patient; and

a telemetry system for communicating information from the control system to the medical device.

Claim 195. (New) A closed loop medical device for a patient for sampling and determining the concentration of a substance of interest in the patient from among the group of biological chemicals, enzymes, and hormones, and for taking an appropriate action in response thereto comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being connected to the sensor module by a wire;

a medical device for taking an action appropriate to a concentration of interest in a patient; and

a telemetry system for communicating information from the control system to the medical device.

Claim 196. (New) A closed loop medical device for a patient for determining the concentration of a substance of interest in the patient from among the group of biological chemicals, enzymes, and hormones, and for taking an appropriate action in response thereto comprising:

means for determining the concentration of a substance of interest in the patient;

means for determining an appropriate response to the determined concentration of the substance of interest;

a medical device for taking an action appropriate to a concentration of interest in a patient;

means for communicating information from the means for determining the concentration to the means for determining an appropriate response; and,

means for communicating information from the means for determining an appropriate response to the medical device.

Claim 197. (New) A closed loop medical device as in claim 196 in which the sensor module or sensor or concentration determining means determines concentration of substances from among the group of drugs of Table 4 of U.S. Patent No. 5,730,714.

Claim 198. (New) A method of treating a medical condition in a patient comprising the steps of:

providing: a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the implantable drug pump;

determining the concentration of a substance of interest including glucose;

comparing the determined concentration of the substance of interest to a predetermined limit;

determining an appropriate response to the determined concentration of the substance of interest;

communicating the determined appropriate response to the medicament pump.

Claim 199. (New) The method of claim 198 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament to the patient.

Claim 200. (New) The method of claim 199 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament including insulin to the patient.



Claim 201. (New) A method of treating a medical condition in a patient comprising the steps of: providing:

a sensor module for determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the implantable drug pump;

determining the concentration of a substance of interest;

comparing the determined concentration of the substance of interest to a predetermined limit;

determining an appropriate response to the determined concentration of the substance of interest;

taking the appropriate response by action by the drug pump.

Claim 202. (New) The method of claim 201 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament to the patient.

Claim 203. (New) The method of claim 201 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament including insulin to the patient.

Claim 204. (New) A method of treating a medical condition in a patient comprising the steps of: providing:

a sensor module for determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response the determined concentration of the substance of interest;

a medical device for taking an action appropriate to a concentration of interest in a patient;

means for communicating information from the sensor module to the control system; and,  
means for communicating information from the control system to the medical device;

determining the concentration of a substance of interest;

comparing the determined concentration of the substance of interest to a predetermined limit;

determining an appropriate response by the medical device to the determined concentration of the substance of interest;

taking the appropriate response by action by the medical device.

Claim 205. (New) The method of claim 204 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament to the patient.

Claim 206. (New) The method of claim 205 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament including insulin to the patient.